SAMPLE PRESENTATION UNIT

Background of the Invention

Area of the Art

The invention relates generally to sample handling mechanisms for automated chemical analyzers, and specifically to a sample presentation unit for automated immunodiagnostic instruments.

Description of the Prior Art

Automated chemical analyzers and automated immunodiagnostic instruments are widely used in clinical chemistry sampling and analyzing applications, and often involve the presentation of samples for performing various assays. Many automated analyzers and immunodiagnostic instruments require automated loading systems for sample presentation. Therefore, some of the requirements of the sample loading system are that the system has a common appearance and functionalities, and is adaptable or easily modifiable to adapt to various immunodiagnostic instruments.

Another requirement of an automated sample loading system is that the system must be able to quickly detect a motor jam during operation to avoid mistakes or damages to the samples.

In addition, it is a requirement of an automated sample loading system to read sample identifications often presented in bar code labels ahead of time to allow information to be downloaded from the common host computer that controls the operation of the immunodiagnostic instrument.

While many mechanisms have been developed for handling samples, they all have certain limitations and therefore cannot satisfy all of the requirements and needs addressed by the present invention. Therefore, it is desirable to provide a new system for presenting samples for processing and analyzing by the immunodiagnostic instruments.

Summary of the Invention

It is an object of the present invention to provide a system for presenting samples to automated chemical analyzers.

The objects and advantages of the present invention are achieved in a sample presentation unit by having a sample rack onload section, a sample rack presentation section, and a sample rack offload section all connected as one unit.

The sample rack onload section has an elongated rail having a distal end and a proximal end, an onload pusher driven by an onload motor and movable along the rail for moving the sample racks placed on the rail towards the proximal end of the rail, and an onload sensor located adjacent to the proximal end of the rail of the sample rack onload section for detection of motion errors or jams of the onload moving mechanism.

The sample rack presentation section has a transfer area connected to the proximal end of the rail of the sample rack onload section for receiving the sample racks from the sample rack onload section, a sample presentation area adjacent to the automated analyzer for presenting sample racks for aspiration, an alignment mechanism for precise positioning of sample tubes, a presentation tray driven by a presentation motor and movable between the transfer area and the presentation area for simultaneously moving a multiplicity of the sample racks from the transfer area to the presentation area for sample aspiration and subsequently moving the multiplicity of the sample racks from the presentation area back to the transfer area after sample aspiration, and a presentation sensor located at the presentation area of the sample rack presentation section for the detection of motion errors or jams of the presentation moving mechanism.

The sample rack offload section has an offload area connected to the transfer area of the sample rack presentation section for receiving the sample racks from the sample rack presentation section after sample aspiration, an offload pusher driven by an offload motor for moving the sample racks received from the sample rack presentation section to a sample rack offload tray, and an offload sensor located at the offload queue area of the sample rack offload section for the detection of motion errors or jams of the offload moving mechanism.

The sample presentation unit of the present invention may also have a bar code reader located adjacent to the transfer area of the sample rack presentation section for

obtaining the identification of the sample racks prior to presenting the sample racks to the automated analyzer for aspiration.

Such an arrangement has been found to provide a number of advantages. As explained in greater detail below, the sample presentation unit of the present invention is a modular system that can be moved away to provide access to other components of the automated analyzer. Since the entire system can be moved together, all alignment information will stay intact.

The modular system design of the sample presentation unit of the present invention also provides a common appearance and functionalities, and is adaptable or easily modifiable to adapt to various automated chemical or immunodiagnostic analyzers.

In addition, the sample presentation unit of the present invention employs strategically located sensors for the quick detection of a motor jam during operation to avoid mistakes or damages to the samples.

Furthermore, the sample presentation unit of the present invention is capable of reading sample identifications ahead of time to allow information to be downloaded from the main host computer that controls the operation of the immunodiagnostic instrument.

The sample presentation unit of the present invention may be used in connection with any automated chemical or immunodiagnostic analyzers that require sample presentations. Examples of such analyzers include, but are not limited to, Access® Special Chemistry Analyzer (Beckman Coulter Inc., CA), and SYNCHRON LX®20 General Chemistry Analyzer (Beckman Coulter Inc., CA), and the like.

The invention is defined in its fullest scope in the appended claims and is described below in its preferred embodiments.

Description of the Figures

The above-mentioned and other features of this invention and the manner of obtaining them will become more apparent, and will be best understood by reference to the following description, taken in conjunction with the accompanying drawings. These drawings depict only a typical embodiment of the invention and do not therefore limit its scope. The drawings serve to add specificity and detail, in which:

FIG. 1 is an illustrative perspective view of a preferred embodiment of the sample presentation unit of the present invention (with the modular unit cover shown), showing sample tubes loaded for presentation;

FIG. 2 is an illustrative perspective view of a preferred embodiment of the sample presentation unit of the present invention (with the modular unit cover and front panel removed to show the internal structure), showing sample tubes loaded for presentation for aspiration;

FIG. 3 is an illustrative top view of a preferred embodiment of the sample presentation unit of the present invention, showing sample tubes loaded for presentation;

FIG. 4 is an illustrative perspective view of a preferred embodiment of the sample presentation unit of the present invention, showing sample tubes loaded for presentation for aspiration;

FIG. 5 is an illustrative perspective view of a sample rack used with the sample presentation unit of the present invention, showing the engagement feature of the sample rack;

FIG. 6 is an illustrative perspective view showing the alignment mechanism of the sample presentation unit of the present invention;

FIG. 7 is an illustrative side elevation view showing the alignment mechanism of the sample presentation unit of the present invention; and

FIG. 8 is an illustrative top view of a preferred embodiment of the sample presentation unit of the present invention, showing the sample presentation unit of the present invention may have an offload area that is split into two linked areas.

Detailed Description of the Invention

The present invention is directed to a new sample presentation unit (SPU) used in conjunction with an automated chemical or immunodiagnostic analyzer.

The SPU of the present invention is used to transport the entire required test samples to and from a main sample aliquoting station of an automated analyzer. The SPU accepts samples in racks that have the capacity for up to, for example, four (4) tubes or sample cups. The racks are identified with user-oriented bar codes. The racks can be loaded on the SPU, either individually or in groups. Following the sample aspiration, the racks can be unloaded singly or as a group.

In general, the sample presentation unit of the present invention has a sample rack onload section, a sample rack presentation section, and a sample rack offload section, all connected as one unit.

The sample rack onload section of the present invention has an onload queue area, and an onload moving mechanism for moving the sample racks placed on the onload queue area to the sample rack presentation section.

The sample rack presentation section of the present invention has a transfer area connected to the onload queue area of the sample rack onload section for receiving the sample racks from the sample rack onload section, a sample presentation area adjacent to the automated analyzer for presenting sample racks for aspiration, a presentation moving mechanism movable between the transfer area and the presentation area for simultaneously moving a multiplicity of the sample racks from the transfer area to the presentation area for sample aspiration and subsequently moving the multiplicity of the sample racks from the presentation area back to the transfer area after sample aspiration, and an alignment mechanism to provide precise sample tube positioning during aspiration.

The sample rack offload section of the present invention has an offload section connected to the transfer area of the sample rack presentation section for receiving the sample racks from the sample rack presentation section after a sample aspiration, and an offload moving mechanism for moving the sample racks received from the sample rack presentation section to a sample rack offload tray.

Offload mechanism adds additional offload capacity by allowing the racks to "wrap" around the instrument. There are racks in the offload section on both sides of the offload moving mechanism.

The sample presentation unit of the present invention is provided with a bar code reader(s) for ascertaining sample rack identifications prior to presenting the sample racks for aspiration.

Having thus provided an overview of a certain embodiment of the present invention, this specification now provides a more detailed discussion of the preferred embodiments of the present invention with particular reference to the drawings.

Referring to Figures 1 through 4, there is shown an SPU **10** of the present invention that may be used in connection with an automated chemical analyzer, such as Access® Special Chemistry Analyzer, described above. The SPU **10** includes three (3)

main interconnected modules or sections: an onload section **12**, a presentation section **14**, and an offload section **16**.

The onload section **12** of the SPU **10** has an elongated rail **18** with a distal end **20** and a proximal end **22**, an onload motor **24**, an onload pusher **26**, and an onload sensor **28** located near the proximal end **22** of the rail **18**.

When the cycle begins, the onload pusher **26** is moved by the onload motor **24** back to its "home" position near the distal end **20** of the rail **18**. Sample racks **4** having an engagement feature **6** and holding multiple (typically 4) sample tubes **2** (as shown in Figure 5) may be placed anywhere on the onload rail **18** as long as there is room available. Priority samples may be placed close to the proximal end **22** of the rail **18**. These racks consist of the "onload queue" **30**.

Once the onload queue **30** is ready, the onload pusher **26** is moved by the onload motor **24** along the rail **18** to push the entire onload queue **30** towards the proximal end **22** of the rail **18** to the presentation section **14** of the SPU **10**. During a run, this will also push any racks in a transfer area of the presentation section **14**, as well as any racks in an offload staging area of the offload section **16** to an offload queue area of the offload section **16**.

As the onload queue **30** is pushed towards the presentation section **14**, the onload sensor **28** looks for the leading edge of a rack to determine if there are more sample racks to be run. If a rack is detected, it will then look for the trailing edge of the rack. Once the trailing edge is detected, the onload pusher **26** will continue moving another fixed distance to bring this rack to a transfer area of the presentation section **14**.

The presentation section **14** of the SPU **10** has the transfer area **32**, an aspiration area **34**, a presentation motor **36**, a presentation tray **38**, a bar code reader (BCR) **40** located near the transfer area **32**, and a presentation sensor **42** located at the remote end of the aspiration area **34**.

Variations in a sample tube position during aspiration from a sample tube **2** with a spherical- or conical- shaped bottom often prevent the sample probe from reaching its full depth inside the sample tube **2**, resulting in increased dead volume or wasted sample. To ensure the precise positioning of the sample tube during aspiration, the present invention sample presentation unit **10** utilizes an alignment mechanism **60** to provide repeatable rack positions, which in turn provides precise sample tube positioning. Referring to Figures 5

through 7, the alignment mechanism **60** includes an alignment block **62** with precision machined "lead-in" slots **64** which can engage with the engagement feature **6** of the sample racks **4**, and spring-biased plungers **66** which force the sample racks **4** against an alignment rail **68**. At the same time the sample racks **4** are forced against the alignment rail **68**, the "lead-in" feature **64** of the alignment block **62** forces the sample racks **4** to transport along the rail **68** into their final aspiration positions. By controlling the position and squareness of the sample racks **4**, the precise positioning of all sample tubes **2** in the sample racks **4** are achieved. In addition, the distance between the lead-in slots **64** on the alignment block **62** is designed slightly wider than the width of each sample rack **4**, such that when all sample racks **4** are engaged with the alignment block **62**, they are slightly separated to make sure that they do not touch and interfere with each other during aspiration.

When the cycle begins, the presentation tray **38** is moved by the presentation motor **36** back to its "home" position at the transfer area **32**, which also pushes a gate **13** (as shown in Figure 2) of the presentation section **14** out of the way. After the leading racks of the onload queue **30** are pushed into the transfer area **32**, the presentation tray **38** is moved forward by the presentation motor **36** to present these sample racks to the aspirate position for sample aliquoting by the main sample aliquoting station of the chemistry analyzer. BCR **40** reads the bar code label of the racks. The sample racks are properly aligned by the alignment mechanism **60,** as described in detail above.

The presentation sensor **42** is provided to detect the status of the presentation motor **36**. If the presentation motor **36** functions normally, then the presentation sensor **42** will be interrupted within a predetermined range before the presented racks get to the aspirate area **34**; otherwise, there is a motion error or motor jam.

The offload section **16** of the SPU **10** has the offload staging area **44**, an offload queue area **46**, an offload motor **48**, an offload pusher **50**, an offload sensor **52** located near the offload queue area **46**, and an offload tray **54**.

The present invention SPU **10** may have two (2) distinct offload areas. One of these areas may be simply an extension of the onload and presentation rails. The other area may be perpendicular to the onload and presentation rails. This creates an additional challenge to the stability of the racks. While on the onload rails, the racks are suspended by features well above the center of gravity of the racks, making it impossible for them to

fall or tip. When the racks are moved perpendicular to the onload and presentation rail, they are no longer suspended but rather sit on the bottom of the racks. This creates the problem of rack stability as they are being advanced by the offload pusher or during rack removal by the operator. To solve this problem, a series of thin protruding fins are provided extending up from the offload surface. These fins are adequately tall and spaced apart such that when a rack is placed between the fins, the rack is stabilized and cannot be tipped. When transitioning into the fins, adequate lead-in is provided on the racks and fins to compensate for slight errors in rack position.

When the cycle begins, the offload pusher **50** is moved by the offload motor **48** back to its "home" position at the offload queue area **46**. The offload sensor **52** is used to determine whether the offload queue area **46** is full. If the offload queue area **46** is full, then the offload motor **48** will move the offload pusher **50** forward to push, for example, four (4) racks in the offload queue area **46** into the offload tray **54**. The offload motor **48** will then move the offload pusher **50** back to its home position. However, before the offload pusher **50** gets back to its home position, the offload sensor **52** must be interrupted within a predetermined range; otherwise, it is an indication of a motion error or motor jam.

The SPU **10** is capable of allowing routine sample racks to be added during a run. When routine sample racks need to be added during a run, the onload pusher **26** will be moved by the onload motor **24** back to its home position. The operators can then add sample racks anywhere on the onload rail **18** as long as there is room available. "Priority" or "semi-priority" sample racks may be placed in front of the onload queue **30**. During routine loading, the operator is locked out of the presentation section by the gate **13** and an enclosed aspiration area **15** (as shown in Figure 2). The instrument can continue all operations with the presentation section during routine loading.

The SPU **10** is also capable of allowing very high priority sample racks to be added during a run. When high priority sample racks need to be added during a run, the operator initiates this loading operation by pressing a switch, then the onload pusher **26** is moved by the onload motor **24** back to its home position, and the presentation tray **38** is also moved by the presentation motor **36** back to its loading position. Then the operator can manually push any sample racks in the presentation tray **42** out of the transfer area **32** of the presentation section **14** and any racks on the rail **18** of the onload section **12** all the way towards the distal end **20** of the onload rail **18**. The operator can then place STAT sample

racks in front of the onload queue. If there is not enough room, the operator can remove some routine sample racks from the onload rail **18** to make room.

The sample presentation unit of the present invention is provided with the necessary electrical and electronic means for power supply, micro-processor control, and connection with the automated analyzer's main control system for integrated control and operation, all of which are evident to one skilled in the art in view of the instant disclosure.

The sample presentation unit of the present invention has many unique and advantageous features, including the modular system design that provides a common appearance and functionalities, and is adaptable or easily modifiable to adapt to various immunodiagnostic instruments, and that can be moved away to provide access to other components of the immunodiagnostic instrument while maintaining all alignment information.

In order to obtain adequate onload and offload rack capacity on an SPU, the SPU can become quite lengthy. One way to accommodate this is to combine the two offload query areas described above and effectively wrap the SPU module around the analyzer. This creates an additional problem because in many applications, the SPU would be in the front of an analyzer and therefore block service and maintenance access to the rest of the analyzer. To solve this problem, the present invention SPU **10** may be broken between the two offload areas, as shown in Figure 8. The primary portion **70** of the SPU **10** containing the onload section, the presentation section, and the "in-line" offload area can be swung or rotated out away from the analyzer. In order to swing out the primary portion **70**, the perpendicular offload area **72** is first transported out of the way. These motion areas are accomplished by adding a linkage connection **74** connecting the primary portion **70** and the perpendicular offload area **72** of the SPU **10**. When the primary portion **70** is swung open, the linkage connection **74** drives the perpendicular offload area **72** ahead of it. When the primary portion **70** is swung back, the linkage connection **74** tightly connects the two portions together.

In addition, the sample presentation unit of the present invention is capable of the quick detection of motion errors or motor jams during operation through the use of strategically located sensors, and is also capable of ascertaining sample identifications ahead of time to allow information to be downloaded from the main host computer that controls the operation of the immunodiagnostic instrument. Automated analyzers can

request test information from a host computer system to avoid manual station entry if data. Host computers may have a time lag of several minutes from being supplied a sample identification to its reply containing test request information. This test request information is necessary to determine what to do with a sample at the time of aspiration. To overcome this time lag, which could seriously diminish total test throughput, the SPU **10** is capable of moving multiple (for example, four) sample racks into the aspiration area **34**. When a subject rack is initially brought into the aspiration area **34**, it passes the bar code reader **40** and the query for the required tested information is sent to the host computer. Meanwhile, the aspiration processes for the three racks ahead of the subject rack are running, and by the time the subject rack is up for aspiration, the test request information for the subject tray from the host computer is returned. Using this technique, sample identifications are read well in advance of the actual aspiration. Since during a routine loading operation the aspiration area is protected from operator intervention, the sample order integrity is maintained.

The foregoing is meant to illustrate, but not to limit, the scope of the invention. Indeed, those of ordinary skill in the art can readily envision and produce further embodiments, based on the teachings herein, without undue experimentation. Suitable materials are commercially available and would be known to those of ordinary skill in the art in view of this disclosure.

It is to be understood that the form of the device depicted in the figures has been chosen only for the purpose of describing a particular embodiment and function of the invention, and that the material of the invention can be addressed in various ways and incorporated in other types of devices, all of which will be evident to those working in the art.

The present invention may be embodied in other specific forms without departing from its essential characteristics. The described embodiment is to be considered in all respects only as illustrative and not as restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of the equivalence of the claims are to be embraced within their scope.